Eur J Vasc Endovasc Surg **32,** 279–285 (2006)
doi:10.1016/j.ejvs.2006.04.029, available online at http://www.sciencedirect.com on SCIENCE DIRECT®

Certification of Vascular Centers – A Project of the German Society for Vascular Surgery

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Objectives. *Due to the progress vascular medicine has made in conventional vascular surgery, endovascular procedures, and conservative therapy close, interdisciplinary cooperation is required. In order to assure the contextual and structural quality of vascular centers, the German Society for Vascular Surgery established a list of criteria for certification of each interdisciplinary vascular center.*
Material and methods. *Between July 2002 and December 2005, 77 centers have submitted a written application and have been audited by the commission for quality assurance of the German Society for Vascular Surgery, 59 vascular centers were certified for a period of 3 years with one center in each in Austria and in Switzerland, 13 centers were not certified (16.8%), and the applications of 5 centers are still pending. This analysis is based on 57 German certified vascular centers.*
Results. *Each center treats a median of 1149 inpatients (11% of these are emergency admissions) and 2159 outpatients per year. Sixty percent of the patients treated have an arterial disease. All centers have vascular surgery and radiology departments. In 11 out of 57 centers, angiology services are offered in cooperation with affiliated physicians. Each vascular center has an average of 4.2 vascular surgeons, 3 radiologists and 1 angiologist. All centers offer radiological and ultrasound diagnostics (CT angiography in 100%, MRT in 95%, duplex sonography in 100%). Each clinic executes a median of 521 (233–1436) arterial operations and 263 (37–1055) arterial interventions. In addition, they execute varicose surgeries* (n = *217), shunt applications/revisions* (n = *58), minor amputations* (n = *57) and major amputations* (n = *42). They conduct 338 (92–3606) conservative therapies per year (POAD, diabetic foot, phlebothrombosis, chronic venous insufficiency).*
Conclusions. *The certification of interdisciplinary vascular centers is a new approach to assure the contextual and structural quality of interdisciplinary vascular centers.*

Keywords: Vascular center; Certification.

Introduction

Interdisciplinary competence centers for the treatment of vascular diseases were created in response to rapid advancements in diagnosis and therapy, changing epidemiology, as well as different political and economic conditions.[1]

During the past few years, there has been groundbreaking progress regarding treatment options for vascular diseases. This progress does not only refer to diagnosis (color-coded Duplex-sonograms, MR-angiography with contrast medium, CT-angiography), but also to therapeutic possibilities. Vascular patients are treated by various different disciplines, but only vascular surgery and angiology exclusively deal with vascular diseases. Now, the optimal, appropriate treatment of vascular patients requires the physician to have a profound understanding of all therapeutic options and regular interdisciplinary exchange among physicians.

Due to demographic changes including a higher life expectancy, there is a disproportionate increase of illnesses resulting from arteriosclerosis. This is true for the peripheral occlusive arterial disease (prevalence up to age 70 about 15%, over 75 >20%), abdominal aortic aneurysm (<1% in men under 60, about 10% after age 80) and for >50% extracranial carotid stenoses (adult population 1–3%, as of age 65 about 8%). What should also be noted is the increasing prevalence of diabetes mellitus (in Germany about 5–6%,

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1078–5884/000279 + 07 $35.00/0

in the US about 8%) as well as primary varicosis (prevalence about 30%, advanced chronic, venous insufficiency 3–4%).[2–6]

Patients, family members, and referring physicians, but also health insurers and politicians increasingly demand interdisciplinary and multidisciplinary treatment. These expectations do not only refer to optimal diagnosis and therapy, but also to the treatment of epiphenomena and the anticipation of possible future vascular complications. This demand for 'integrated care' consequently also includes the expectation that all therapy options (operative–endovascular–conservative) are offered with the respective expertise and weighed against each other, keeping the interest of the patient as the focus.[7,8]

The introduction of a diagnosis – related compensation system additionally lead to an increased 'economization' of all hospital processes. In order to secure their position, hospitals need to try to avoid multiple exams, establish short, concentrated inpatient therapy focusing on core services (invasive diagnostics, OR, intensive therapy etc.), which manages to overcome inflexible departmental structures, and transfer most of the diagnostic testing to outpatient centers. In addition, there needs to be a close cooperation with affiliated specialists, general care practitioners, and institutions for after care (key word: integrated care).

The term 'center' stands for competent physicians and nursing staff, interdisciplinary facilities as well as care around the clock (24 hours a day/7 days a week) for emergencies. Not every self-proclaimed center can meet these standards. In order to assure the contextual quality of a vascular center, the German Society for Vascular Surgery established criteria for the foundation and certification of vascular centers in 2002 and 2004. It finalized the application form in 2003, and made it available in database format since June 2005. The requirement cataloge, as seen in Table 1, describes the structural and clinical conditions that are, from the point of view of the German Society for Vascular Surgery, required for the creation of a vascular center. The operative case load is based on the continuing education regulation. But case numbers by themselves are not the only factor. These are weighed against other factors, such as the location of the center (rural/urban area), documented method variety, degree of interdisciplinary cooperation (e.g. case conferences, collaboration with affiliated physicians).[9,10]

Table 1. Vascular Center Standards, as per German Society for Vascular Surgery

Emergency cases	■ Diagnostics and therapy 'around the clock'
Required specialties	■ Vascular Surgery ■ Diagnostic/interventional radiology ■ Angiology
Quality assurance	■ CEA, AAA
Adequate case numbers	■ >800 inpatient/outpatient vascular patients/year (of which >500 with arterial diseases) ■ >400 inpatient cases
Technology-aided diagnostics	■ CT, MRT, intraarterial angiography ■ Doppler-, Duplex-sonography ■ Treadmill ergometry
Operative case numbers	■ >30 supraaortic arteries ■ >20 abdominal aortic procedures ■ >35 iliac and/or inguinal reconstructions ■ >35 femoro-popliteal reconstructions ■ >20 distal bypasses ■ >20 combination procedures (surgical/endovascular)
Intervention case numbers	■ >100 PTA/Stent-implantations (iliac a., femoral a., renal a., carotid a., subclavian a.) ■ peripheral catheter lysis
Conservative therapy case numbers	■ >50 cases with PAOD ■ >25 cases with diabetic foot ■ >50 cases with chronic-venous insufficiency ■ >25 cases with deep vein thrombosis (DVT)
Training licenses	■ 3 years for vascular surgery (exception 2 years)* ■ As much training as possible for radiology, angiology, and phlebology

*Since 2006 vascular surgery is an own specialty with a minimum of 4 years training.

Material and Methods

The certification of the vascular center is based on a written application, which requires information regarding statistics (outpatient and inpatient cases, operations, interventions, conservative cases, emergencies, etc.), diagnosis-related processes and structures (specialized units, cooperation partners, staff physicians etc.). After verification of the application by the commission for quality assurance, the secretary of the German Society for Vascular Surgery (DGG) or a commission member audits the clinic and prepares a written report. The final decision is based on a DGG board resolution.

The first vascular center was certified on 1/1/2003. In July 2003 and June 2005, we revised the application form in order to achieve a higher degree of comparability and documentation of the applications. By December 31st, 2005, the quality assurance commission had processed 77 applications, among them 2 applications from Switzerland and Austria and 5

reapplications after initial rejection. Five applications are still pending. Fiftynine centers were certified by the DGG after an audit and the preparation of a written report (HI, HHE, TN, HPN), 13 applications were denied (percentage of denied applications 16.8%, Table 2, Fig. 1) for the following reasons: missing round-the-clock emergency care, low case numbers, predominance of varicose surgery and hardly any arterial therapy. The fee for the application and audit is € 2,500. The certificate is valid for 3 years. This paper presents an analysis of the first 57 German certified vascular centers (two centers weres certified in Switzerland and Austria respectively).

Results

Case numbers and structure of German vascular centers

Case numbers: The median number of patients treated annually in DGG certified vascular centers is 3619. Nearly 60 percent of the patients have arterial diseases, 30 percent have illnesses related to the venous system (varices, phlebothrombosis). The remainder includes lymphatic illnesses, inflammatory vascular diseases and the non-vascular diabetic foot. The median number for inpatients is 1149/year with a median hospital stay of 10 days. 11 percent of all inpatients were admitted by the emergency room. The centers see about 2159 outpatients per year and conduct 120 outpatient operations (varices, i.v. port, shunt applications) (Table 3).

Disciplines: In 36 vascular centers, vascular surgery is an independent clinic or department (In 11 cases, they are combined with thoracic surgery). In 21 centers, it is a part of the general surgical department (of which 5× as an independent section/area). Only 3 centers have an independent angiology unit, and 5 centers have sections or areas for angiology. Eleven out of 57 centers cooperate with affiliated physicians specialized in angiology. In the remaining centers, angiology is part of the internal medicine or cardiology department. In 12 centers no specialized angiologists are available, either within the hospital or as affiliated physicians. In these centers internal physicians ($n = 10$) or vascular surgerons ($n = 2$, rural areas) are responsible for the conservative treatment of vascular diseases. On average, there are 8 (4–18) physicians working in vascular surgery with 4.2 specialized vascular surgeons (2–8). The radiology units have an average of 3 (2–9) specialized radiologists, which are sometimes responsible solely for vascular

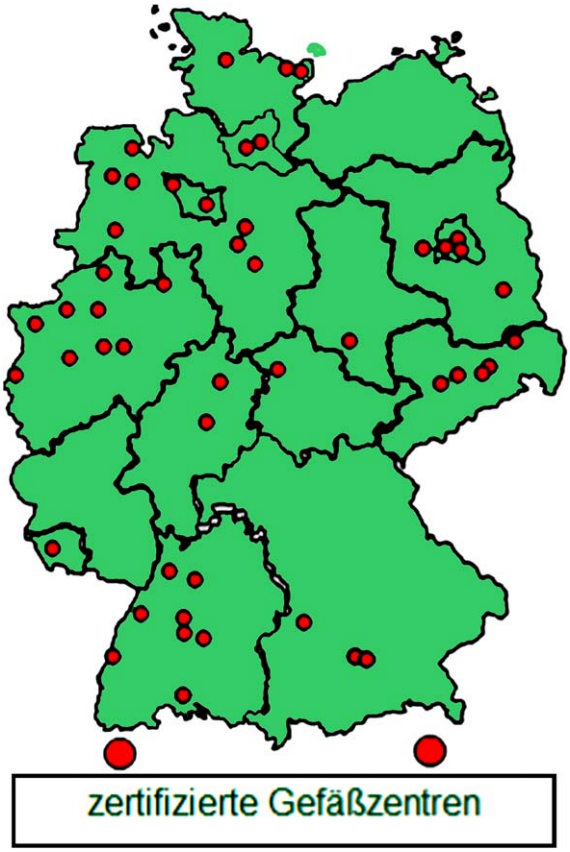

Fig. 1. Map showing all vascular centers in Germany ($n = 57$, Austria ($n = 1$) and Switzerland ($n = 1$) that were certified by December 31st 2005 (www.gefaesschirurgie.de).

Table 2. Applications for certification as approved vascular center since July 2002

Time period	All applications	Certification denied	Certified
Jan–June 2003	16	3	13
July–Dec 2003	6	–	6
Jan–June 2004	11	2	9
July–Dec 2004	18	5	13
Jan–June 2005	9	1	8
July–Dec 2005	17	2	10*
	77	13	59

*Five applications are pending.

Table 3. Amount of patients in 57 certified german vascular centers

	Cases/year (Median)
All vascular patients	3619
Patients with arterial diseases	2065
Patients with venous diseases	861
Vascular inpatients	1149
Percentage emergency cases*	11%
Inpatient Stay	10 days
Outpatient contacts	2159
Outpatient operations	120

*All immediate admissions (acute ischemia, ruptured AAA, phlebothrombosis etc.).

radiology, but most are responsible for radiology in general. Internal medicine departments have an average of 6 (0–22) physicians, that mainly deal with general internal or cardiologic cases. An average of 1 (0–5) physicians are designated angiologists.

The following disciplines are represented in almost all centers, either as an internal cooperation partner (hospital department) or as an external partner: Neurology (stroke, carotid stenosis), nephrology (dialysis, shunt operations), cardiology, diabetology and anesthesiology.

Interdisciplinary conferences: 30 centers conduct daily case conferences, 10 centers have them 2-3 times per week, and 17 centers conduct one conference per week.

Amount of Beds: Fourty beds are available in the vascular surgical units (Median, at least 10, at the most 130). So far, it has not been possible to find out how many dedicated 'vascular beds' there are in other departments.

Continuing Education Opportunities: 53 of 57 centers offer a 3-year continuing education opportunity with regard to vascular surgery (in 4 centers only 2 years). In 40 centers, it is possible to receive a complete radiology training whereas complete angiology training can be received in only 19 centers. In 24 centers, it is possible to be trained in phlebology.

Technology-aided diagnostics

The data are given in Table 4. CT, intra-arterial angiography and an ultrasound diagnostic set-up (Doppler and Duplex Sonogram) is available in all centers, MRT and MR-Angiography in 95%. Eightyfour percent of all centers have the capacity for a transcranial Doppler Sonogram. Two thirds of all centers have advanced venous testing capabilities with venous pressure measurements and/or venous occlusion plethysmography.

Therapies

Table 5 gives the amount of open surgical procedures, endovascular interventions and conservative treatments. Variations exist in terms of the total numbers of procedures and the relationship between operative and interventional procedures although in general an increase in open surgical procedures was echoed by an increase in endovascular procedures as well (Fig. 2) In 46 centers endovascular therapy is done by vascular radiologists (percutaneous procedures) and vascular surgeons (intraoperative endovascular procedures) respectively. In 11 centers, angiologists and/or cardiologists conduct catheter-supported interventions together with radiologists and vascular surgeons.

Table 4. Available equipment and case numbers for radiological and sonographic diagnostics and treadmill ergometry (57 certified german vascular centers)

	Available equipment	Cases/year (Median, Min–Max)
Intraarterial angiography (supraaortic, peripheral)	100%	750 (115–1967)
Computer-tomographyn (brain, large vessels)	100%	1545 (79–9631)
Cervical MRT and MR-angiography	95%	387 (0–5122)
Intraoperative angiography	100%	132 (20–1300)
Duplex sonography (arteries and veins)	100%	3099 (485–1476)
Transcranial Doppler-sonography (TCD)	84%	49 (0–3844)
Treadmill ergometry	100%	350 (0–3113)

Quality assurance

When applying for certification all centers took part in quality assurance projects (100% in a nationwide registry on CEA.[11] 74% (42/57) in an AAA-registry and 52% (30/57) in a registry for varicose vein surgery respectively. Since the latter registries are run by the German Society of Vascular Surgery all applying

Table 5. Amount of open surgical and endovascular procedures and conservative treatments (57 certified german vascular centers)

	Cases/year (Median, Min–Max)
Conventional surgical arterial reconstructions	521 (233–1436)
Carotid endarterectomy	89 (35–372)
Aortic reconstructions (AAA, PAOD)	51 (17–150)
Reconstruction of iliac a./inguinal bifurcation	93 (21–425)
Infrainguinal reconstructions	105 (30–364)
Varicose surgery	220 (56–2884)
Shunt applications/revisions	58 (0–376)
Major amputations	42 (2–98)
Endovascular arterial reconstructions	263 (37–1055)
Supraaortic interventions (carotid a., subclavian a.)	9 (0–204)
Abdominal aortic aneurysm (EVAR)	5 (0–66)
PTA/Stent lower extremity (iliac, femoral, popliteal arteries),	206 (30–926)
Thrombolysis (local lyse, aspiration lyses)	20 (0–113)
All conservative therapies	338 (53–3606)
PAOD (only inpatient treatment)	141 (20–2500)
Diabetic foot	69 (6–495)
Deep vein thrombosis	97 (0–600)
Chronic-venous insufficiency (CVI)	74 (0–1800)

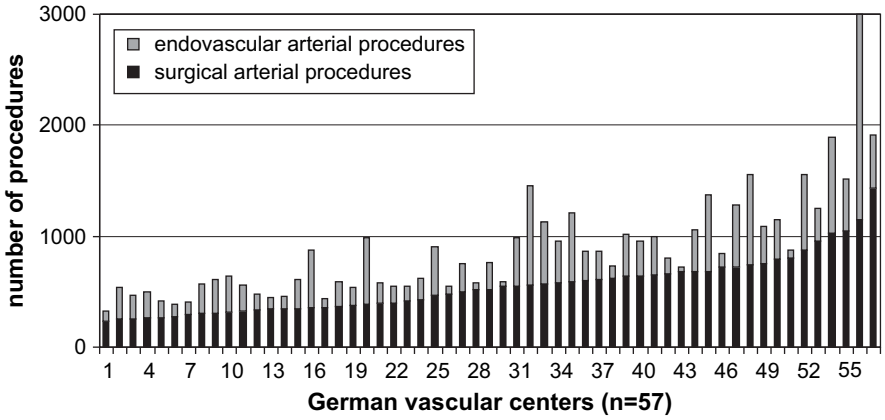

Fig. 2. Distribution of conventianal arterial operative reconstructions (median $n = 521$) and endovascular arterial procedures (median $n = 263$) in 57 German certified vascular centers.

centres were obliged to participate immediately not only in the CEA-registry but also in the AAA and varicose vein surgery registries. In a further publication we will analyse and compare the perioperative outcomes in carotid surgery and AAA surgery (e.g. morbidity, mortality, length of stay) in certified and non-certified vascular centers respectively.

Discussion

The term ''Vascular center''started to appear in the professional literature in the mid 90s, predominantly in American publications. The interdisciplinary cooperation mainly referred to vascular surgery and interventional radiology.[12,3,9,4,13,14] The reasons for the formation of such centers were the growing possibilities through catheter intervention, economic reasons, as well as increased competition between the clinics.[12,15,13,16,1,14,17,18] In Germany, the first call for a closer cooperation was done in 1998.[19] The first concrete experiences regarding interdisciplinary structures were made in Hamburg-Harburg and Munich.[20] Since then, many clinics have adopted the concept for the formation of interdisciplinary vascular centers, but without the existence of any generally accepted standards (case numbers, result quality, amount of cooperation etc.).[8] Unfortunately, the term 'vascular center' was used by some colleagues to improve their own position among the competition without assuring that the center provided the necessary essential services (emergency care, interdisciplinarity etc.).

The goal of the project ''certification of vascular centers' is to review structures and case load data in vascular centers, and to qualify them through a certification process. The unexpectedly high resonance (77 applications since July 2002) supports the DGG's endeavors. Since then, DGG has been able to certify 59 centers: 57 in Germany, and 1 in Switzerland and in Austria each.

Limitations

Although the certified vascular centers provide care for a large amount of vascular patients this project resulted in some points of concern and criticism:

As all vascular centers provide sufficient vascular surgical and radiological services angiology is represented less frequently. The 2004 physicians statistics of the ''Bundesärztekammer'' revealed that 488 specialised angiologists are working in Germany of whom only 292 are working within a hospital. By comparison 811 vascular surgeons and 2439 radiologists are working within hospitals.[21] This significant lower number of angiologists might explain that trained angiologists are not available in all areas. It is the policy of DGG to certify these center only, if they are able to prove that their internal/cardiologic units (or vascular surgical unit in two cases) perform conservative vascular therapy and that the angiology services either within or ouside the hospital will be established within the coming 3 years (before recertification). Combined certifications and joint audits by all vascular disciplines might be helpful to overcome this limitation. This possibility is currently being examined by the German Radiology Association (DRG), the German Society for Vascular Surgery (DGG) and the German Society for Angiology (DGA).[7]

The clinical documentation regarding case numbers and services is unfortunately not uniform, and is done with the individual clinic's hospital informational system and/or individual documentation modules. In addition some processes and services may not be assigned to the individual patient, which

might be especially true for diagnostic procedures (patient-related amounts of CCTs, angiographies, etc.). These circumstances raise concerns regarding the comparability of the given data.

The quality of a vascular center should ultimately be based on above-average result quality. Several studies indicate a positive volume-outcome relationship for major vascular surgical procedures like AAA surgery, CEA and peripheral bypass surgery.[22] Since high volume centers for some reasons may not always have better results the board of the German Society for Vascular Surgery decided that morbidity and mortality rates regarding CEA, AAA surgery and interventional procedures should be part of the future certification and recertification process. Currently the results of CEA and AAA procedures in certified vascular centers are being analysed retrospectively and will be published in a subsequent paper.

Re-certification

All centers must recertify after 3 years in order to assure continued compliance with the required quality criteria. Another audit have to be done, if there were relevant changes regarding staffing or structural conditions (such as a new director, newly-founded department etc.). The recertification also serves to find out if the weaknesses and deficiencies that were found during the first certification process have been removed (such as training certifications, case numbers, angiology representation, missing quality assurance etc.). These centers will also have to be audited again.

Perspectives

Due to the above mentioned limitations regarding data collection, we devised a 3rd version of the application form, which will be used for initial applications and request for recertification as of June 2005. The new form is based on a databank program (FileMaker). It can be downloaded from the society's home page, and is submitted to the DGG office via the internet.[23] Some of the main changes or additions include a more exact capture of the center's interdisciplinarity (documentation from interdisciplinary case conferences, clinical processes), the verifiability of training and accreditation by the association of physicians in private practises, a far-reaching documentation of results (rate of complications regarding CEA, surgery for AAA and PTA) as well as a more sophisticated presentation of the operative, endovascular, and conservative services rendered (especially patient-relevant procedures). Thus, there will be an increased transparency, data validity, and comparability of the individual centers.

Conclusions

Our data allow some preliminary conclusions:

(1) The unexspected high number of applications for certification and the large amount of vascular patients and examinations indicate that the concept of an interdiscipinary vascular center is attractive for hospitals, physicians and patients.
(2) In the vast majority of centers vascular surgery, radiology and angiology are represented appropriately, even though the number of surgeons and radiologists within a center is significantly higher than the number of angiologists.
(3) The ultimate goal of a vascular center should be to achieve above-average results. Therefore the assessment of outcome data in surgical and interventional procedures will be an essential part of the certification in the future.

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Accepted 21 April 2006
Available online 15 June 2006